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99933581.3-1222/US9914486

Anmelder/Applicant/Demandeur/Patentinhaber/Propriétaire/Titulaire  
Virologic, Inc.

## COMMUNICATION

The European Patent Office herewith transmits the partial European search report under Rule 46(1) EPC relating to the above-mentioned European patent application.

Copies of the documents cited in the search report are enclosed.

The applicant's attention is drawn to the following:

The search Division informs the applicant that if the European search report is also to cover inventions other than the invention first mentioned in the claims, a further search fee must be paid for each of these inventions, within ONE MONTH after notification of this communication.

If the application has been filed up to 30 June 1999, the search fee in force before 01 July 1999 (EUR 869.--) or the equivalent applicable on the date of payment is payable.

This applies also to the search fees requested under Rule 46(1) EPC.  
See also OJ EPO 08/1999, 405.

☐ The abstract was modified by the Search Division and the definitive text is attached to the present communication.

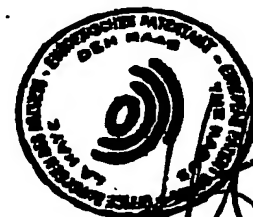
☒ Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

### Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 02/1999.

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**SUPPLEMENTARY  
PARTIAL EUROPEAN SEARCH REPORT**

under Rule 46, paragraph 1 of the European Patent Convention  
Application Number  
**EP 99 93 3581**

DOCUMENTS CONSIDERED TO BE RELEVANT		
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim
X	WO 97/27332 A (INNOGENETICS NV ; STUYVER LIEVEN (BE); LOUWAGIE JOOST (BE); ROSSAU RUD) 31 July 1997 (1997-07-31)	1-7
Y	* page 4, line 15 - page 5, line 11 *	17, 18, 20-31
	* page 6, line 16 - page 7, line 15 *	
	* page 13, line 26 - line 29 *	
	* page 22, line 19 - line 21 *	
	* tables 1-3 *	
D, Y	WO 97/27319 A (VIROLOGIC INC) 31 July 1997 (1997-07-31)	17, 18
	* claims 1, 5, 12, 28, 32, 33, 88, 90, 93 *	
	-/-	

CLASSIFICATION OF THE APPLICATION (INCL.6)
C12Q1/68 C12Q1/70 C12N13/00 C07H21/02 C07H21/04 A01N43/04

TECHNICAL FIELDS SEARCHED (INCL.6)
C12Q

**LACK OF UNITY OF INVENTION**

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

The present partial European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.

Place of search	Date of completion of the search	Examiner
The Hague	24 September 2004	Schmitt, A

**CATEGORY OF CITED DOCUMENTS**

X: particularly relevant if taken alone  
Y: particularly relevant if combined with another document of the same category  
A: technological background  
O: non-written disclosure  
P: intermediate document

T: theory or principle underlying the invention  
E: earlier patent document, but published on, or after the filing date  
D: document cited in the application  
L: document cited for other reasons  
&: member of the same patent family, corresponding document



DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int. Cl. 6)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	
Y	IVERSEN A K N ET AL: "MULTIDRUG-RESISTANT HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 STRAINS RESULTING FROM COMBINATION ANTIRETROVIRAL THERAPY" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 70, no. 2, 1 February 1996 (1996-02-01), pages 1086-1090, XP002031823 ISSN: 0022-538X * the whole document *	17, 18, 22-25, 28-31	
A		1-7, 20, 21, 26, 27	
Y	FITZGIBOON J E ET AL: "HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 POL GENE MUTATIONS IN AN AIDS PATIENT TREATED WITH MULTIPLE ANTIRETROVIRAL DRUGS" JOURNAL OF VIROLOGY, THE AMERICAN SOCIETY FOR MICROBIOLOGY, US, vol. 67, no. 12, December 1995 (1995-12), pages 7271-7275, XP002934804 ISSN: 0022-538X * the whole document *	20, 21, 24-27	TECHNICAL FIELDS SEARCHED (Int. Cl. 6)
Y	CLERCQ DE E: "DEVELOPMENT OF RESISTANCE OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TO ANTI-HIV AGENTS: HOW TO PREVENT THE PROBLEM?" INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS, AMSTERDAM, NL, vol. 9, no. 1, 1997, pages 21-36, XP000878561 ISSN: 0924-8579 * the whole document *	17, 18	
A		1-7, 20-31	



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# PARTIAL EUROPEAN SEARCH REPORT

Application Number  
EP 99 93 3581

DOCUMENTS CONSIDERED TO BE RELEVANT		Relevant to claim	CLASSIFICATION OF THE APPLICATION (In.CLO)
Category	Citation of document with indication, where appropriate, of relevant passages		TECHNICAL FIELDS SEARCHED (In.CLO)
A	KANKI P J ET AL: "VIROLOGY OF HIV-1 AND HIV-2: IMPLICATIONS FOR AFRICA" AIDS, LONDON, GB, vol. 11, no. SUPPL B, 1997, pages S33-S42, XP008035289 ISSN: 0269-9370 * the whole document *		

EPO FORM 1500 (12.02) (PHE/19) 3



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. claims: 1-7, 17, 18, 20-31 (completely)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV reverse transcriptase (HIV-RT) having a mutation/insertion at codon 69, or at codons 69, 41, 215, or at codons 69, 62, 215, or at codons 69, 62, 74, or at codons 69, 41, 215, 210 (210, 75; 62; 62, 210); and method and resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codon(s).

2. claims: 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 62 or at codon 62 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codon(s).

3. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 75 or at codon 75 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

4. claims: Claims 8 - 16, 19 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 77 or at codon 77 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

5. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 116 or at codon 116 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

6. claims: Claims 8 - 16, 19 (partially)

Method for assessing the effectiveness of nucleoside reverse transcriptase antiretroviral therapy of an HIV-infected patient comprising evaluating whether a patient plasma sample contains nucleic acid encoding HIV-RT having a mutation at codon 151 or at codon 151 and further codons; and method and/or resistance test vector for assessing the biological effectiveness of a candidate HIV antiretroviral drug compound comprising a patient-derived segment of reverse transcriptase which comprises a mutation at said codons.

The single general concept possibly linking inventions 1 to 6 appears to be the provision of methods and/or products for assessing drug effectiveness involving HIV-RT having a mutation at a certain codon. Methods and/or products for assessing drug effectiveness involving HIV-RT having a mutation at a certain codon are already disclosed in the prior art (cf. WO 97/27332 A: p. 4, l. 15 - p. 5, l. 6; Tables 1 - 3; cf. IVERSEN A K N et al. (1996): Table 1; cf. FITZGIBOON J E et al (1995): tables 1, 2; cf. DE CLERCQ E (1997): Tables 2 - 5). Therefore, the Search Division is of the opinion that the above defined single general concept lacks novelty and thus does not represent a single general inventive concept. Hence, the present application lacks unity



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

(Art. 82 EPC).

No further features shared by the 6 inventions listed above could be identified by the Search Division, which would be considered to be special technical features in the sense of Rule 30 EPC. Hence, the 6 inventions listed above are not unitary according to Article 82 EPC.

# ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO.

EP 99 93 3581

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on  
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24-09-2004

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9727332	A	31-07-1997	AU 719691 B2	18-05-2000
			AU 1444397 A	20-08-1997
			BR 9704637 A	09-06-1998
			CA 2215073 A1	31-07-1997
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			EP 0817866 A1	14-01-1998
			JP 11502727 T	09-03-1999
			US 6331389 B1	18-12-2001
			US 6087093 A	11-07-2000
			US 2003077575 A1	24-04-2003
WO 9727319	A	31-07-1997	AU 732255 B2	12-04-2001
			AU 1952897 A	20-08-1997
			CA 2216126 A1	31-07-1997
			CN 1213407 A	07-04-1999
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			JP 2000503849 T	04-04-2000
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			PL 328068 A1	04-01-1999
			RO 118887 B1	30-12-2003
			WO 9727319 A1	31-07-1997



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